

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,398 11/10/2003		Shutsung Liao	10634-002002 / UCHI 751 C	4394
26161 7590 02/05/2007 FISH & RICHARDSON PC			EXAMINER	
P.O. BOX 1022	2		BADIO, BARBARA P	
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3 MONTHS		02/05/2007	DADED	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/705,398	LIAO ET AL.			
Office Action Summary	Examiner	Art Unit			
	Barbara P. Badio, Ph.D.	1617			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timwill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status		•			
1) Responsive to communication(s) filed on	<u>_</u> .				
2a) This action is FINAL . 2b) ⊠ This	☐ This action is FINAL . 2b)⊠ This action is non-final.				
3) Since this application is in condition for allowa	nce except for formal matters, pro	secution as to the merits is			
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposition of Claims					
 4) Claim(s) 18,20-23,29,31-34,65 and 66 is/are pending in the application. 4a) Of the above claim(s) 23 and 33 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 18,20-22,29,31,32 and 65 is/are rejected. 7) Claim(s) 34 and 66 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 					
Application Papers		·			
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	epted or b) objected to by the Education of the Education of the drawing of the d	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)					
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: See Continua	ite atent Application			

Continuation of Attachment(s) 6). Other: Raw sequence listing error report.

Application/Control Number: 10/705,398 Page 2

Art Unit: 1617

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2006 has been entered.

Status of the Application

- 2. Claims 18, 20-23, 29, 31-34, 65 and 66 are pending in the present application. Claims 23 and 33 stand withdrawn from further consideration as being drawn to a nonelected species. Claims 18, 20-22, 29, 31, 32, 34, 65 and 66 will be examined according to MPEP § 803.02.
- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. The rejection of claims 18, 20-22, 29, 31, 32 and 65 under 35 USC 102(b) over Kurosawa et al. is withdrawn.

Application/Control Number: 10/705,398 Page 3

Art Unit: 1617

5. The rejection of claims 18, 20-22, 29, 31, 32 and 65 under 35 USC 102(b) over Cohen-Solal is withdrawn.

6. Claims 18, 20-22, 29, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shen et al. (1990).

Shen et al. teaches several steroid derivatives including (24S)-24-methyl-5 β -cholest-22-ene-3 α ,6 α ,24-triol; 3 α ,6 α -diacetoxy-24-methyl-5 β -cholest-23-ene-22-one and (22R)-24-methyl-5 β -choles-23-ene-3 α ,6 α ,22-triol (see the entire article, especially page 1766, compounds 4-7). The compounds taught by the reference are encompassed by the instant claims.

7. Claims 18, 20-22, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (1992).

Zhou et al. teaches several steroid derivatives including 3α , 6α -dimethoxymethyloxy- 5β -25-methyl-choles-22(E)-en-24-one and methyl-22,23-didehydrohyodeoxycholate (see the entire article, especially pages 1839-1840, compounds 11, 12, 22, 25, 26, 27, etc.). The compounds taught by the reference are encompassed by the instant claims.

8. Claims 18, 22, 29, 31. 32 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Iorizzi et al. (1995).

Art Unit: 1617

lorizzi et al. teaches steroid derivatives including 24-methyl- 5α -cholesta-22-en- 3β , 5, 6β , 15α , 26-pentaol-26-sulfate, isolated from starfish *Luidia clathrata* and their effect on various bacteria (see the entire article, especially Abstract; page 654, compounds 7, 8, etc.). The compounds and compositions taught by the reference are encompassed by the instant claims.

Claim Objections

9. Claims 34 and 66 are objected to as being dependent upon a rejected base claim.

Note: The claims are allowable to the extent they read on the elected species.

Other Matters

10. Please find enclosed a copy of raw sequence listing error report.

Telephone Inquiry

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/705,398 Page 5

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB February 2, 2007

STIC Biotechnology Systems Branch

RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/705,398Source: 1FW16Date Processed by STIC: 06/16/2005

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.
PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE <u>CHECKER</u> <u>VERSION 4.2.2 PROGRAM</u>, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail. Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

- 1. EFS-Bio (http://www.uspto.gov/ebc/efs/downloads/documents.htm, EFS Submission User Manual ePAVE)
- 2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
- 3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 01/14/05): U.S. Patent and Trademark Office, Mail Stop Sequence, Customer Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314

Revised 01/24/05

Raw Sequence Listing Error Summary

PDDAD DEMY COURT	10/205 200
ERROR DETECTED	suggested correction serial number: 10/705,398
ATTN: NEW RULES CASES	S: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE
lWrapped Nucleics Wrapped Aminos	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."
2Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.
3Misaligned Amino Numbering	The numbering under each 5 th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.
4Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.
5Variable Length	Sequence(s) contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.
6PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.
7Skipped Sequences (OLD RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped
	Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.
8Skipped Sequences (NEW RULES)	Sequence(s) missing. If intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000
9Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
Respense	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence
	Sequence(s) missing the <220> "Feature" and associated numeric identifiers and responses. "Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)
· bug"	Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.
13 Misuse of n/Xaa	"n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid



IFW16

RAW SEQUENCE LISTINGPATENT APPLICATION: **US/10/705,398**DATE: 06/16/2005

TIME: 12:16:36

Input Set : A:\10634-002002.txt

Output Set: N:\CRF4\06162005\J705398.raw

```
4 <110> APPLICANT: Liao, Shutsung
              Song, Ching
      8 <120> TITLE OF INVENTION: STEROID DERIVATIVES
     11 <130> FILE REFERENCE: 10634-002002
                                                                 Does Not Comply
     13 <140> CURRENT APPLICATION NUMBER: US 10/705,398
C--> 14 <141> CURRENT FILING DATE: 2203-11-10
                                                                 Corrected Diskette Needed
     16 <150> PRIOR APPLICATION NUMBER: US 09/560,236
     17 <151> PRIOR FILING DATE: 2000-04-28
     19 <150> PRIOR APPLICATION NUMBER: US 60/191,864
     20 <151> PRIOR FILING DATE: 2000-03-24
     22 <150> PRIOR APPLICATION NUMBER: US 60/131,728
     23 <151> PRIOR FILING DATE: 1999-04-30
     26 <160> NUMBER OF SEQ ID NOS: 12
     28 <170> SOFTWARE: FastSEQ for Windows Version 4.0
     30 <210> SEQ ID NO: 1
     31 <211> LENGTH: 16
     32 <212> TYPE: DNA
     33 <213> ORGANISM: Artificial Sequence
     35 <220> FEATURE:
     36 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     38 <220> FEATURE:
     39 <221> NAME/KEY: misc feature
     40 <222> LOCATION: 7-10
     41 <223> OTHER INFORMATION: n = a, g, t \text{ or } c
     43 <400> SEQUENCE: 1
W--> 44 aggtcannnn aggtca
                                                                           16
     47 <210> SEQ ID NO: 2
     48 <211> LENGTH: 57
     49 <212> TYPE: DNA
     50 <213> ORGANISM: Artificial Sequence
     52 <220> FEATURE:
     53 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     55 <220> FEATURE:
     56 <221> NAME/KEY: misc_feature
     57 <222> LOCATION: 16-18, 22-27, 34-39
     58 <223> OTHER INFORMATION: n =a, g, t or c
     60 <400> SEQUENCE: 2
W--> 61 gtatcgccgg aattennntt gnnnnnnttg ttgnnnnnnt aagtcgacte tagagee
     63 <210> SEQ ID NO: 3
     64 <211> LENGTH: 57
     65 <212> TYPE: DNA
     66 <213> ORGANISM: Artificial Sequence
     68 <220> FEATURE:
```

DATE: 06/16/2005

```
TIME: 12:16:36
                     PATENT APPLICATION: US/10/705,398
                     Input Set : A:\10634-002002.txt
                     Output Set: N:\CRF4\06162005\J705398.raw
     69 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     71 <220> FEATURE:
     72 <221> NAME/KEY: misc_feature
     73 <222> LOCATION: 19-24, 31-36, 40-43
     74 <223> OTHER INFORMATION: n = a, g, t \text{ or } c
     76 <400> SEQUENCE: 3
W--> 77 ggctctagag tcgacttann nnnncaacaa nnnnnncaan nngaattccg gcgatac
     79 <210> SEQ ID NO: 4
     80 <211> LENGTH: 57
     81 <212> TYPE: DNA
     82 <213> ORGANISM: Artificial Sequence
     84 <220> FEATURE:
     85 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     87 <400> SEQUENCE: 4
     88 gtategeegg aatteatett geacagattg ttgcaagaat aagtegaete tagagee
     90 <210> SEQ ID NO: 5
     91 <211> LENGTH: 57
     92 <212> TYPE: DNA
     93 <213> ORGANISM: Artificial Sequence
     95 <220> FEATURE:
     96 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     98 <400> SEQUENCE: 5
     99 ggctctagag tcgacttatt cttgcaacaa tctgtgcaag atgaattccg gcgatac
                                                                            57
     101 <210> SEQ ID NO: 6
     102 <211> LENGTH: 60
     103 <212> TYPE: DNA
     104 <213> ORGANISM: Artificial Sequence
     106 <220> FEATURE:
     107 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     109 <220> FEATURE:
     110 <221> NAME/KEY: misc feature
     111 <222> LOCATION: 16-18, 22-27, 37-42
     112 <223> OTHER INFORMATION: n = a, g, t or c
     114 <400> SEQUENCE: 6
W--> 115 gtategeegg aattennntt gnnnnnntgg ttgttgnnnn nntaagtega etetagagee 60
     118 <210> SEQ ID NO: 7
     119 <211> LENGTH: 60
     120 <212> TYPE: DNA
     121 <213> ORGANISM: Artificial Sequence
     123 <220> FEATURE:
     124 <223> OTHER INFORMATION: Synthetically generated oligonucleotide
     126 <220> FEATURE:
     127 <221> NAME/KEY: misc feature
     128 <222> LOCATION: 19-24, 34-39, 43-45
     129 <223> OTHER INFORMATION: n = a, g, t \text{ or } c
     131 <400> SEQUENCE: 7
W--> 132 ggctctagag tcgacttann nnnncaacaa ccannnnnnc aannngaatt ccggcgatac 60
     135 <210> SEQ ID NO: 8
     136 <211> LENGTH: 5
```

RAW SEQUENCE LISTING

DATE: 06/16/2005

TIME: 12:16:36

Input Set : A:\10634-002002.txt Output Set: N:\CRF4\06162005\J705398.raw Invalid Response See dem # 11 en Sammary Sheet 137 <212> TYPE: PRT 138 <213> ORGANISM: Artificial Sequence 140 <220> FEATURE: 141 <223 > OTHER INFORMATION: Motif 143 <220> FEATURE: 144 <221> NAME/KEY: VARIANT 145 <222> LOCATION: 2, 3 146 <223> OTHER INFORMATION: Xaa = any amino acid 148 <400> SEQUENCE: 8 W--> 149 Leu Xaa Xaa Leu Leu 150 1 153 <210> SEQ ID NO: 9 154 <211> LENGTH: 6 Same Error 155 <212> TYPE: PRT 156 <213> ORGANISM: Artificial Sequence 158 <220> FEATURE: 159 <223> OTHER INFORMATION: Motif 161 <220> FEATURE: 162 <221> NAME/KEY: VARIANT 163 <222> LOCATION: 2, 3 164 <223> OTHER INFORMATION: Xaa = any amino acid 166 <400> SEQUENCE: 9 W--> 167 Leu Xaa Xaa Trp Leu Leu 168 1 171 <210> SEQ ID NO: 10 172 <211> LENGTH: 26 173 <212> TYPE: DNA 174 <213> ORGANISM: Artificial Sequence 176 <220> FEATURE: 177 <223> OTHER INFORMATION: Synthetically generated oligonucleotide 179 <400> SEQUENCE: 10 180 ttcaggtcac aggaggtcag agagct 26 182 <210> SEQ ID NO: 11 183 <211> LENGTH: 27 184 <212> TYPE: DNA 185 <213> ORGANISM: Artificial Sequence 187 <220> FEATURE: 188 <223> OTHER INFORMATION: Synthetically generated oligonucleotide 190 <400> SEQUENCE: 11 191 tcgagtctgg tacagggtgt tcttttg 27 193 <210> SEQ ID NO: 12 194 <211> LENGTH: 16 195 <212> TYPE: DNA 196 <213> ORGANISM: Artificial Sequence 198 <220> FEATURE: 199 <223> OTHER INFORMATION: Synthetically generated oligonucleotide 201 <400> SEQUENCE: 12 202 aggtcaagcc aggtca 16

RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/705,398

RAW SEQUENCE LISTING ERROR SUMMARY DATE: 06/16/2005 PATENT APPLICATION: US/10/705,398 TIME: 12:16:37

Input Set : A:\10634-002002.txt

Output Set: N:\CRF4\06162005\J705398.raw

Please Note:

Use of n and/or Xaa have been detected in the Sequence Listing. Please review the Sequence Listing to ensure that a corresponding explanation is presented in the <220> to <223> fields of each sequence which presents at least one n or Xaa.

Seq#:1; N Pos. 7,8,9,10/
Seq#:2; N Pos. 16,17,18,22,23,24,25,26,27,34,35,36,37,38,39
Seq#:3; N Pos. 19,20,21,22,23,24,25,26,27,34,35,36,40,41,42
Seq#:6; N Pos. 16,17,18,22,23,24,25,26,27,34,38,39,40,41,42
Seq#:7; N Pos. 19,20,21,22,23,24,34,35,36,37,38,39,43,44,45
Seq#:8; Xaa Pos. 2,3
Seq#:9; Xaa Pos. 2,3

VERIFICATION SUMMARY DATE: 06/16/2005 PATENT APPLICATION: US/10/705,398 TIME: 12:16:37

Input Set : A:\10634-002002.txt

Output Set: N:\CRF4\06162005\J705398.raw

L:14 M:271 C: Current Filing Date differs, Replaced Current Filing Date
L:44 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:1 after pos.:0
L:61 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:2 after pos.:0
L:77 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:3 after pos.:0
L:115 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:6 after pos.:0
L:132 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:7 after pos.:0
L:149 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:8 after pos.:0
L:167 M:341 W: (46) "n" or "Xaa" used, for SEQ ID#:9 after pos.:0